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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/928,464 | 08/13/2001 | William J. Boyle | ACS-57080 | 6454 |

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| EXAMINER |
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MCCORKLE, MELISSA A

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| ART UNIT | PAPER NUMBER |
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3763

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 04/17/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/928,464

Applicant(s)

BOYLE ET AL.

Examiner

Melissa A. McCorkle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 6, 9-28, 30, 34-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-8, 29, 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-5 and 7-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Wade (6,273,716.) Wade discloses an elongate tube 10. He discloses a resealable longitudinal joint (fig 3B left side) having a first side extending substantially along the length of the elongate tube and a second side extending opposite the first side, (34a and 34b) the second side having an opening 54 extending substantially along the length of the elongate tube, the first side having an outwardly extending protrusion 52 extending substantially along the length of the elongate tube, the protrusion adapted to fit within the opening, the protrusion has a neck leading to a head, the head being larger than the neck, and the opening leads to a cavity, the opening being smaller than the head of the first side and at least as large as the neck of the first side, and the cavity being within a range of slightly smaller to larger than the head of the first side; the elongate tube having a single lumen, the longitudinal joint extending throughout an entire length of the sheath; the longitudinal joint extending from a proximal end of the sheath to a position proximal a distal end of the sheath; the longitudinal joint having a depth extending from an external surface of the sheath to a surface of the lumen. It is

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inherent that the lumen is capable of being pressurized up to and over 8atm since dental handpieces use highly pressurized water and air.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 29 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al (6,080,141) in view of Wade (6,273,716). Castro discloses all of applicant's basic inventive concept of a convertible delivery system for medical devices substantially as claimed, with the exception of the sheath being resealable. Wade discloses this feature to be old in the medical devices art. He teaches a protective sheath that is resealable as claimed. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to make the sheath resealable from the teachings of Wade for the purpose of using the sheath over again.

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6. Castro discloses a sheath including an elongate tube with a joint, a guidewire [col 5 line 60] distributed through the at least one lumen, a handle 16, a device 15 coupling the proximal portion of the sheath to a distal portion of the handle, a device configured to split the longitudinal joint and to allow the sheath to be removed from the guidewire [col 5 line 32], the splitting device further comprising a ring having a lumen, the ring fitting over the sheath, and a blade aligned with a longitudinal axis of the ring and being coupled to the surface of the lumen of the ring, a height of the blade being sufficient to extend into the lumen of the sheath and including a distal edge for cutting the sheath during relative longitudinal movement between the ring and the sheath; the ring further comprising a guide mandrel 50 coupled to the edge of the blade, the guide mandrel configured to be positioned within the lumen of the sheath; the device coupling the proximal portion of the sheath to the distal portion of the handle is split along the length of the device (fig 1-2, col 4 line 56-column 7 line 5).

Conclusion


7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 9:00am - 5:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


NICHOLAS D. LUCCHESI
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Melissa A McCorkle
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